IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. BASIC RESET and BIOGENYX, sole proprietorships, and FRED R. KAUFMAN III and KIMBERLY KAUFMAN, individuals, Defendants.	)	**COMPLAINT FOR PERMANENT INJUNCTION** Civil No. _____

COMPLAINT

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Basic Reset and Biogenyx, sole proprietorships (together, "Basic Reset/Biogenyx" or the "company") and Fred R. Kaufman III and Kimberly Kaufman, individuals (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343;

C. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

D. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a device, as defined in 21 U.S.C. § 321(h), that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o).

2. Defendants label and distribute various types of products, including drugs, dietary supplements, and a device. Defendants distribute their products to consumers nationwide from a facility in Hendersonville, Tennessee.

3. Certain of Defendants' products are drugs under the Act because they are intended for use in diagnosing, curing, mitigating, treating, or preventing disease, such as inflammation, chronic diarrhea, bacterial infections, head lice, and allergies, or because they are intended to affect the structure or function of the body, such as toning muscles. Defendants' drugs are unapproved new drugs because they are not generally recognized as safe and effective, not approved by FDA, and not exempt from the approval requirements.

4. Defendants' dietary supplements are adulterated because they are prepared, packed, or held under conditions that are not in conformance with the current good manufacturing practice

regulations for dietary supplements that are intended to ensure the quality of dietary supplements. In addition, some of Defendants' dietary supplements are misbranded because their labels do not contain information required by law.

5. Defendants distribute a medical device that is adulterated because there is no approved application for premarket approval on file with FDA and it does not fall within an exemption from this requirement, and misbranded because Defendants failed to notify FDA of their intent to introduce the device into interstate commerce for commercial distribution.

6. Beginning in 2012, FDA made Mr. Kaufman aware that he was violating the Act, ultimately sending a Warning Letter in 2016. Despite repeated promises to fix the problems, Defendants have not done so. Accordingly, the United States now seeks a permanent injunction to bring Defendants' operations into compliance with the law.

Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

8. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

9. Defendant Basic Reset/Biogenyx is composed of two sole proprietorships, Basic Reset and Biogenyx. Mr. Kaufman registered both sole proprietorships with the State of Tennessee on April 29, 2019. Mr. Kaufman previously operated Basic Reset and Biogenyx as Tennessee corporations, Basic Reset Inc. and Biogenyx, Inc. Mr. Kaufman dissolved Basic Reset Inc. and Biogenyx, Inc. on April 30, 2019, and the corporations were terminated on May 17, 2019, and May 23, 2019, respectively. Basic Reset/Biogenyx does business at 260 W. Main Street,

Suites 103 and 106D, Hendersonville, Tennessee 37075 (the "Facility"), within the jurisdiction of this Court.

10. Fred R. Kaufman III is the sole proprietor of Basic Reset/Biogenyx, and had been the president and owner of Basic Reset, Inc. and Biogenyx, Inc. He is the most responsible person at the company and handles everything outside of customer service, including but not limited to, website maintenance, product inquiries, finances, contract manufacturer communications, and has the ability to hire and fire employees. Mr. Kaufman performs his duties at the Facility, within the jurisdiction of this Court.

11. Kimberly Kaufman launched Basic Reset, Inc. with Mr. Kaufman in 2015. *See* About Us, Basic Reset, https://www.basicreset.com/aboutus (last visited July 24, 2019). Prior to the dissolution of Basic Reset, Inc. and Biogenyx, Inc. in April 2019, Ms. Kaufman served as the treasurer for these corporations. Her duties at Basic Reset/Biogenyx include banking, assisting distributors, and approving labels. She performs some of her duties at the Facility, within the jurisdiction of this Court.

12. Basic Reset/Biogenyx is an own label distributor of various types of products, including drugs, dietary supplements, and a device. Basic Reset/Biogenyx's products include, but are not limited to, AquaLyte, Bee Gold, Beta Factor, Body Mass Reset, CBD Reset, Dino-Min, Earth Wash, Energy FX, GH-C, Ionyte, Mello-Tonin, Miracle Facelift Masque, Nuovi Firming Masque, Nuovi Skin Toner, pH-FX, Q-min, SlimUp, TrimUp, and Vibrant Energy Drink.

13. Basic Reset/Biogenyx uses several different contract manufacturers to manufacture the products it distributes. Some of Defendants' products arrive pre-labeled from contract manufacturers; however, Defendants also label many of their products in-house.

14. Defendants receive their products from out-of-state contract manufacturers, including from New Mexico and Florida. Defendants distribute their products to customers in various states, including Arizona, Georgia, and Maryland.

15. Basic Reset/Biogenyx operates as a multi-level marketer. Basic Reset/Biogenyx provides each "affiliate" with a website (affiliate name.basicreset.com). The websites for the affiliates, according to Mr. Kaufman, are maintained by Basic Reset/Biogenyx. Basic Reset/Biogenyx also maintains a company website (www.basicreset.com), which is registered to Mr. Kaufman and makes representations about Defendants' products for the treatment of a variety of diseases and/or for use in affecting the structure or function of the body. The company website contains an online store where consumers can purchase Defendants' products directly. Consumers may also purchase products by calling Basic Reset/Biogenyx's office. In addition to the company website, there are several additional websites, such as www.aqualyte.info, www.beegold.info, www.betafactor.info, www.biogenyx.info, www.cbd-reset.info, www.dino-min.info, www.earthwash.info, www.gh-c.info, www.inonyte.info, www.mello-tonin.info, www.nuovi.info, www.ph-fx.info, www.slimupnow.info, and www.trimup.info, which are registered to Mr. Kaufman and include representations about Defendants' products.

Defendants' Violations of the Act

Unapproved New Drugs

16. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C).

17. Because a product's intended use determines whether it is a drug, a product that falls within the Act's dietary supplement definition may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *See* 21 U.S.C. § 321(ff).

18. The Act defines "label" as, *inter alia*, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k), and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

19. Defendants cause many of their products to be drugs within the meaning of the Act because they make claims on their labeling establishing that their products are intended for use in the cure, mitigation, treatment, or prevention of disease ("disease claims").

20. In addition, Defendants cause some of their products (e.g., Nuovi Skin Toner and Nuovi Firming Masque) to be drugs within the meaning of the Act because they make claims on their labeling establishing that their products are intended to affect the structure or function of the body ("structure/function claims").

21. FDA reviewed Defendants' labeling in July 2019 and identified disease claims and structure/function claims, including, but not limited to, the following:

A. Bee Gold: "it can seem like a genuine miracle for people suffering with allergies . . . like myself. Bee pollen was the first dietary supplement I took, after suffering with allergies for 19 years. Finally, for the first time in my life, I felt wonderful, and was able to stop taking allergy shots.";

B. CBD Reset: "been proven to have many health benefits in the areas of . . . chronic pain, inflammation," "I have severe back and neck stiffness from 2 car wrecks, and have

undergone 4 disc replacements and fusion. Nothing I took helped, including other CBD oils, and I spent most days in bed. Starting with Day 1of Reset 2400, the stiffness was almost completely gone! I am mobile again.";

C. Dino-Min: "can help support the body's natural defenses to better deal with such things as: Chronic diarrhea, chronic constipation, gas and bloating Leaky gut syndrome (particles entering the blood that shouldn't) Inflammatory bowel disorders Candida (yeast) overgrowth Bacterial infections Common colds and flu Inflammation throughout the body Autoimmune reactions (immune system attacks the body) Candida (yeast) overgrowth," "Helps support elimination of toxins and heavy metals," "Helps support normal response to pain";

D. Earth Wash: "get rid of head lice";

E. Ionyte: "Helps sooth [sic] cuts, burns, bruises, insect bites and stings";

F. Mello-Tonin: "Helps protect against electromagnetic radiation";

G. Nuovi Firming Masque: "facelift in a bottle," "helps tone the underlying muscles," "helps decrease skin damage," "helps combat acne, inflammation";

H. Nuovi Skin Toner: "helps to soothe cuts, burns, bug bites, bruises, sunburn, and sore muscles";

I. pH-FX: "May Help Support: . . . Body's ability to fight inflammation"; and

J. SlimUp: "helps support . . . healthy cholesterol levels," "helps to support management of inflammation."

22. FDA reviewed Defendants' labeling in March 2019 and identified disease claims and structure/function claims, including but not limited to the following:

A. AquaLyte: "Helps support healthy cholesterol, heart cells, and helps regulate blood sugar," "I had a rash on my back and ankles. The ointments and dermatologist didn't help.

But after just 7 days on AquaLyte the rash was almost gone," "For 15 yrs. I suffered with stomach pain, gas, and tenderness. After 2 days on AquaLyte all the pain was gone and it never came back";

B. Body Mass Reset: "reduces constipation," "helps relieve inflammation of urinary tract," "helps cleanse the body of parasites";

C. GH-C: "A 2009 study out of Auburn University discovered that curcumin is literally 400 times more potent than Metformin (a common diabetes drug) in activating AMPK which helps support healthy insulin sensitivity," "This past year Phytotherapy Research published the results of an amazing study showing curcumin was as effective as Prozac in helping support the body to manage depression";

D. Miracle Facelift Masque: "tightens . . . facial muscles"; and

E. Q-min: "CoQ10 has been used in medical practices for decades, especially in the case of supporting the medical treatment of heart problems."

23. As of July 2019, the products identified in Paragraph 22 no longer appear on Defendants' company website.

24. The claims described in Paragraphs 21 and 22 above demonstrate that these products are drugs because they are intended: (a) to cure, mitigate, treat, or prevent diseases, including inflammation, chronic diarrhea, bacterial infections, head lice, and allergies; and/or (b) to affect the structure or function of the body by, among other things, toning muscles. *See* 21 U.S.C. § 321(g)(1)(B) and (C).

25. A drug is a "new drug" if "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed,

recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of safety and effectiveness. *See* 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

26. Defendants' drugs listed in Paragraphs 21 and 22 above lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that these drugs are GRAS/E for any use and, therefore, qualified experts cannot come to a consensus opinion concerning the effectiveness of these products.

27. Because Defendants' drugs are not GRAS/E, they are new drugs.

28. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or abbreviated new drug application for that drug, or the drug is exempt from approval under an investigational new drug application. *See* 21 U.S.C. § 355(a), (b), (i), and (j).

29. FDA searched its records and found no new drug applications, abbreviated new drug applications, or investigational new drug applications for Defendants' new drugs listed in Paragraphs 21 and 22 above. Moreover, Defendants' drugs do not conform to the OTC monograph set forth in 21 C.F.R. § 330.1, or any other OTC drug monograph. Therefore, Defendants' products are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

30. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

Adulterated Dietary Supplements

31. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). A dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

32. Many of Defendants' products, including AquaLyte, Bee Gold, Beta Factor, Body Mass Reset, Dino-Min, GH-C, Ionyte, Mello-Tonin, SlimUp, TrimUp, and Vibrant Energy Drink fall within the Act's definition of a dietary supplement, because they are not represented for use as a conventional food or as a sole item of a meal, they each contain at least one ingredient that is a "dietary ingredient," as defined in 21 U.S.C. § 321(ff), and they are labeled as dietary supplements.

33. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, or held in conformance with the current good manufacturing practice regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1).

34. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. These regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. These regulations require such persons to control all aspects of their processes and procedures to ensure compliance with

established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

35. FDA investigators inspected Defendants' Facility between October 30 and November 7, 2017 (the "October 2017 Inspection"). The October 2017 Inspection established that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP.

36. During the October 2017 Inspection, FDA investigators documented numerous deviations from the Dietary Supplement CGMP regulations, including but not limited to:

A. Failure to establish specifications to assure that the products they receive for labeling as dietary supplements are adequately identified and consistent with the purchase order (*see* 21 C.F.R. § 111.70(f));

B. Failure to establish specifications for the labeling of their dietary supplements, including specifications to ensure accuracy during the labeling process (*see* 21 C.F.R. § 111.70(g));

C. Failure to establish specifications for their labels (*see* 21 C.F.R. § 111.70(d));

D. Failure to establish and follow written procedures that specify responsibilities for quality control (*see* 21 C.F.R. § 111.103);

E. Failure to identify each unique lot within each shipment of received product in a manner that allows Defendants to trace the lot to the supplier, the date received, the name of the received product, the status of the received product (e.g., quarantined, approved, or rejected), and to the product that Defendants labeled and distributed as dietary supplements (*see* 21 C.F.R. § 111.165(d)(1));

F. Failure to establish and follow written procedures to review and investigate product complaints (*see* 21 C.F.R. § 111.570(b)(2));

G. Failure to make and keep records of any material review and disposition decision on a returned dietary supplement (*see* 21 C.F.R. § 111.535(b)(2)); and

H. Failure to prepare batch production records that document labeling operations at the time Defendants are labeling their products (*see* 21 C.F.R. § 111.260(k)).

37. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

38. Defendants violate 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranded Dietary Supplements

39. The Act deems a dietary supplement to be misbranded unless its label or labeling, among other things: correctly reports the serving size; bears nutrition information in a Supplement Facts panel; properly declares dietary ingredients; provides the name of individual ingredients; declares the percent daily value of ascorbic acid; identifies the product by using the term "dietary supplement"; and includes a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with the dietary supplement. 21 U.S.C. § 343(i)(2), (q)(1)(A), (q)(5)(F), (s)(2)(B), and (y).

40. Several of Defendants' dietary supplements are misbranded within the meaning of the Act, 21 U.S.C. § 343. For example,

A. The labels for Bee Gold, Dino-Min, and TrimUp incorrectly state their serving size in violation of 21 U.S.C. § 343(q)(1)(A), 21 C.F.R. §§ 101.9(b) and 101.12(b);

B. The labels for Bee Gold and Vibrant Energy Drink fail to bear a Supplement Facts panel in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. § 101.36; and

C. The label for Bee Gold improperly declares dietary ingredients that, because they are not present or are present in amounts that can be declared as zero, should not be included on the label in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. §§ 101.36(b)(2) and 101.9(c).

41. As of October 2017, Defendants held for sale and/or distributed additional products that were misbranded within the meaning of the Act, 21 U.S.C. § 343, as follows:

A. The AquaLyte label declared "Coral Minerals," but failed to list each individual ingredient in violation of 21 U.S.C. § 343(i)(2), 21 C.F.R. §§ 101.4(a) and 101.36(c)(2);

B. The label for AquaLyte failed to declare the percent daily value of ascorbic acid, in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. §§ 101.36(b)(2) and 101.9(c)(8)(iv);

C. The label for Body Mass Reset failed to consistently identify the product as a dietary supplement as part of the statement of identity in violation of 21 U.S.C. § 343(s)(2)(B), 21 C.F.R. § 101.3(g); and

D. The label for Body Mass Reset failed to include a street address or phone number through which the responsible person may receive a report of a serious adverse event, in violation of 21 U.S.C. § 343(y).

42. As of July 2019, the products identified in Paragraph 41 no longer appear on Defendants' company website.

43. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343.

44. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become misbranded within the meaning of 21 U.S.C. § 343 while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Adulterated Device

45. The Act defines a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is . . . *intended* for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man . . . or intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h) (emphasis added).

46. Energy FX is "a highly energized, non-toxic (safe enough to drink) liquid inside a pendant that is to be worn as a necklace, carried in a pocket, or attached to your pet's collar." 100-3B Energy FX-Sleek Stainless Steel for Adult, Kids, and Pets, Basic Reset http://www.basicreset.com/index.php?getpage=store&getsec=catalog&page=item&itemid=80&theme=1&xpage=category (last visited July 24, 2019) ("Energy FX Online Catalog Listing").

47. Energy FX is a device within the meaning of the Act, 21 U.S.C. § 321(h), because it is intended for use: (a) in the cure, mitigation, treatment, or prevention of disease, including but not limited to leukemia; and (b) to affect the structure or function of the body of man by, among other things, "strengthen[ing] [consumers] natural bio-energy keeping [consumers] strong against

the onslaught of EMF waves (electromagnetic frequency) produced from electrical devices and Wi-Fi." Energy FX Online Catalog Listing. Additionally, Energy FX does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized, but achieves its primary intended purposes by creating a "Protective Shield Against Electromagnetic Frequencies." *Id.*

48. Defendants' labeling includes the following claims related to Defendants' Energy FX:

A. "[S]trengthen your natural bio-energy, keeping you strong against the onslaught of EMF waves (electromagnetic frequency) produced from electrical devices and Wi-Fi.";

B. "Even if you don't 'feel' any different wearing Energy FX, you can rest assured that you are being protected. Many have reported . . . a decrease in pain."; and

C. "Because of the possible link to childhood leukemia Electormagnetic [sic] Frequencies have been classified as possible carcinogens in 1998 by the National Environmental Health Institute (NIEHS) and in 2001 by the International Agency for Research on Cancer (IARC) of the World Health Organization."

49. The claims described in Paragraph 48 above demonstrate that Defendants' Energy FX is a device within the meaning of the Act because it is intended to cure, mitigate, treat, or prevent diseases or affect the structure or any function of the body of man and achieves its primary intended purposes not through chemical action or by being metabolized.

50. The Medical Device Amendments of 1976 classified medical devices into one of three categories—Class I, II, or III. 21 U.S.C. § 360c. A device's class determines the type of regulatory controls to which it is subject and any review and marketing authorization it must go through prior to marketing.

51. A Class III device is adulterated if: (1) it is required to have in effect an approved application for premarket approval under 21 U.S.C. § 360e(a); (2) there is no FDA-approved application for premarket approval in effect for such device; and (3) it is not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

52. Devices that are introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified into Class III as a matter of law. 21 U.S.C. §§ 360c(f)(1) and 360e(a). Those devices remain in Class III and require premarket approval unless and until FDA, by written order, reclassifies the devices into Class I or II or FDA issues a written order finding the device to be substantially equivalent to a legally marketed predicate device. 21 U.S.C. § 360c(i).

53. FDA determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures set out in 21 U.S.C. § 360(k). *See also* 21 CFR Part 807, Subpart E. In general, manufacturers are required to submit a 510(k) premarket notification for any device that is being introduced into commercial distribution for the first time. 21 C.F.R. § 807.81(a)(1).

54. Alternatively, a sponsor of a device introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, with low to moderate risk may submit a direct *de novo* classification request to FDA to determine whether the device is appropriate for classification into Class I or II if there is no legally marketed predicate device and the sponsor provides information demonstrating that general controls, or a combination of general controls and special controls, are sufficient to provide a reasonable assurance of safety and effectiveness of the device. 21 U.S.C. § 360c(f)(2).

55. Defendants' device, Energy FX, is a Class III device by law because it is a device intended for human use and was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and it does not meet the exemptions set forth in 21 U.S.C. § 360c(f)(1).

56. Defendants' device does not have an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a) or an effective investigational device exemption under 21 U.S.C. § 360j(g).

57. Defendants' device, Energy FX, is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

58. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of a device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

Misbranded Device

59. A device is deemed to be misbranded if a premarket notification for such device was not provided as required under 21 U.S.C. § 360(k). 21 U.S.C. § 352(o).

60. Premarket notification is required for any device that is, *inter alia,* being introduced into commercial distribution for the first time. 21 C.F.R. § 807.81(a)(1).

61. The premarket notification required under 21 U.S.C. § 360(k) is deemed satisfied when a premarket approval application or a *de novo* classification request is pending before FDA. 21 C.F.R. § 807.81(b).

62. Defendants did not submit a premarket notification to FDA for the device that they have been introducing and delivering for introduction, and/or causing the introduction or delivery for introduction, into interstate commerce for commercial distribution.

63. Defendants' device is misbranded within the meaning of 21 U.S.C. § 352(o).

64. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce a device that is misbranded within the meaning of 21 U.S.C. § 352(o).

Previous Violations

65. Defendants have previously been in violation of the Act, as documented by FDA investigators during inspections conducted from April 25–27, 2012 (the "2012 Inspection"), March 2–7, 2016 (the "2016 Inspection"), and March 20–27, 2017 (the "March 2017 Inspection").

66. During these inspections, FDA investigators observed Dietary Supplement CGMP deviations many of which were the same or similar to CGMP deviations observed during FDA's October 2017 Inspection including, but not limited to: the failure to establish specifications, failure to establish a quality control system, and the failure to identify each unique lot within each shipment of received product. Additionally, during the 2012 inspection, FDA investigators identified potential drug claims on Defendants' labeling.

67. FDA repeatedly warned Mr. Kaufman and the company about many of their ongoing violations. At the close of each inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA 483") to, and discussed the observations with, Mr. Kaufman.

68. On July 1, 2016, FDA issued a Warning Letter to Mr. Kaufman and Basic Reset/Biogenyx, informing them that they were introducing into interstate commerce adulterated dietary supplements and misbranded dietary supplements, and described multiple Dietary Supplement CGMP violations and ways in which they had misbranded some of their dietary supplements. The Warning Letter also informed them that they were introducing into interstate commerce unapproved new drugs (AquaLyte, Bee Gold, Beta Factor, and Ionyte).

69. Mr. Kaufman has repeatedly promised to correct the Dietary Supplement CGMP deficiencies observed by FDA. Specifically, in a March 18, 2016 letter, Mr. Kaufman stated that within 90–120 days he would implement resolutions to all observations cited in the 2016 Form FDA 483. But, as discussed above, FDA investigators observed many of the same Dietary Supplement CGMP deficiencies during subsequent inspections. Similarly, in response to the Warning Letter, Mr. Kaufman sent FDA a letter dated July 25, 2016, stating that he had, among other things, "revised [Basic Reset/Biogenyx's] website to remove any reference to medical claims" and "revised product labels to meet requirements." However, during the October 2017 Inspection, FDA found many of the same or similar dietary supplement misbranding issues still ongoing. Additionally, as recently as July 2019, Defendants are still making disease claims and structure/function claims for many of their products. Similarly, in an April 14, 2017, letter to FDA, Mr. Kaufman stated that he had reached out to a law firm that would help him address all the observations cited in the March 2017 Form FDA 483 within the next thirty days. But, as mentioned above, FDA investigators observed many of the same or similar violations during the October 2017 Inspection. Defendants have not responded to the October 2017 Form FDA 483.

70. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (including but not limited to dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343 and a device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o); and

C. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, which such articles are held for sale after shipment of one or more of their components in interstate commerce;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce any drugs, articles of food (including dietary supplements), or devices unless and until:

A. An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drug; or Defendants have removed from (1) labeling; (2) promotional

materials; (3) websites owned, controlled by, or related to Defendants; and (4) any other media over which Defendants have control, all representations about the intended use(s) of Defendants' products that cause such products to be drugs as defined by the Act;

B. Defendants' facilities, methods, processes, and controls used to receive, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP and the Act, in a manner acceptable to FDA;

C. Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations, in a manner acceptable to FDA; and

D. Defendants' device is the subject of an approved application for premarket approval under 21 U.S.C. § 360e(a), the subject of an investigational device exemption under 21 U.S.C. § 360j(g), the subject of a cleared premarket notification under 21 U.S.C. § 360(k), or the subject of a grant of *de novo* classification from FDA under 21 U.S.C. § 360c(f)(2); or Defendants have removed all representations about the intended use(s) of Defendants' product that causes such product to be a device as defined by the Act from (1) labeling; (2) promotional materials; (3) websites owned, controlled by, or related to Defendants; and (4) any other media over which Defendants have control;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the receipt, labeling, holding, and distribution of all of Defendants' products, including drugs, articles of food (including dietary supplements), and devices, to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 26th day of August, 2019.

Respectfully submitted,

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United States Attorney

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JS 44 (Rev. 07/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
United States of America,

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
AUSA Christopher C. Sabis, United States Attorney's Office
110 9th Avenue South, Suite A-961, Nashville, TN 37203
Tel.: (615) 736-5151; E-mail: christopher.sabis@usdoj.gov

DEFENDANTS
BASIC RESET and BIOGENYX, sole proprietorships, and FRED R. KAUFMAN III and KIMBERBERLY KAUFMAN, individuals

County of Residence of First Listed Defendant Sumner County, TN
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a); 21 U.S.C. § 331(d); 21 U.S.C. § 343; etc.

Brief description of cause:
Statutory Injunction proceeding under Federal Food, Drug and Cosmetic Act against named Defendants.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE
08/26/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. BASIC RESET and BIOGENYX, sole proprietorships, and FRED R. KAUFMAN III and KIMBERLY KAUFMAN, individuals, Defendants.	)	**CONSENT DECREE OF PERMANENT INJUNCTION** Civil No. _____

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Basic Reset and Biogenyx, sole proprietorships (together, "Basic Reset/Biogenyx" or the "company") and Fred R. Kaufman III and Kimberly Kaufman, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act").

3. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 ("Dietary Supplement CGMP"); and

B. Misbranded within the meaning of 21 U.S.C. § 343(i)(2), (q)(1)(A), (q)(5)(F), (s)(2)(B), and/or (y), because their labels fail to: list individual ingredients, correctly state the serving size, bear a Supplement Facts panel, properly declare dietary ingredients; declare the percent daily value of ascorbic acid; include a statement of identity as a dietary supplement, and/or include a domestic address or domestic phone number.

4. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and misbranded within the meaning of 21 U.S.C. § 343(i)(2), (q)(1)(A), (q)(5)(F), (s)(2)(B), and/or (y), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

5. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

6. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a device, as defined by 21 U.S.C. § 321(h), that is:

A. Adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), in that it is a Class III device under 21 U.S.C. § 360c(f), and it does not have an approved application for premarket approval on file with the United States Food and Drug Administration ("FDA") as required by

21 U.S.C. § 360e(a) or an effective investigational device exemption under 21 U.S.C. § 360j(g); and

B. Misbranded within the meaning of 21 U.S.C. § 352(o), in that Defendants have failed to provide premarket notification of the device to FDA as required by 21 U.S.C. § 360(k).

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons"), are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, labeling, holding, or distributing any articles of food (including dietary supplements), drugs, or devices at or from 260 W. Main Street, Suites 103 and 106D, Hendersonville, Tennessee 37075, or at or from any other location(s) at which Defendants now or in the future directly or indirectly receive, label, hold, or distribute articles of food (including dietary supplements), drugs, or devices (hereafter, "Defendants' Facility" or "the Facility"), unless and until:

A. For all of Defendants' food (including dietary supplements):

i. Defendants retain, at Defendants' expense, an independent person (the "CGMP Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Facility to determine whether the methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within three (3) business days of retaining such CGMP Expert;

ii. The CGMP Expert performs a comprehensive inspection of the Facility and the methods, processes, and controls used to receive, label, hold, and distribute dietary supplements and certifies in writing to FDA that: (a) he or she has inspected the Facility, methods, processes, and controls; (b) all Dietary Supplement CGMP deviations that have been brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and (c) the Facility and the methods, processes, and controls used to receive, label, hold, and distribute dietary supplements, are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The CGMP Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination that Defendants have created and implemented methods, processes, and controls to ensure that they:

a. Establish specifications to assure that the products they receive for labeling as dietary supplements are adequately identified and consistent with the purchase order, s*ee* 21 C.F.R. § 111.70(f);

b. Establish specifications for the labeling of their dietary supplements, including specifications to ensure accuracy during the labeling process, s*ee* 21 C.F.R. § 111.70(g);

c. Establish specifications for their labels, s*ee* 21 C.F.R. § 111.70(d);

d. Establish and follow written procedures that specify responsibilities for quality control, *see* 21 C.F.R. § 111.103;

e. Identify each unique lot within each shipment of received product in a manner that allows Defendants to trace the lot to the supplier, the date received, the name of

the received product, the status of the received product (*e.g.*, quarantined, approved, or rejected), and to the product that Defendants labeled and distributed as dietary supplements, s*ee* 21 C.F.R. § 111.165(d)(1);

f. Establish and follow written procedures to review and investigate product complaints, *see* 21 C.F.R. § 111.570(b);

g. Make and keep records of any material review and disposition decision on a returned dietary supplement, *see* 21 C.F.R. § 111.535(b)(2); and

h. Prepare batch production records that include documentation of the labeling operations at the time Defendants label their products, *see* 21 C.F.R. § 111.260(k);

iii. Defendants retain, at Defendants' expense, an independent person (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review product labels; labeling; promotional materials; websites owned, controlled by, or related to Defendants including, but not limited to, www.aqualyte.info, www.basicreset.biz, www.basicreset.com, www.basicreset.info, www.basicreset.net, www.basicreset.org, www.beegold.info, www.betafactor.info, www.biogenyx.info, www.cbd-reset.info, www.dino-min.info, www.dorothykaufman.com, www.earthwash.info, www.gh-c.info, www.ionyte.info, www.ionyte.org, www.mello-tonin.info, www.nuovi.info, www.ph-fx.info, www.slimupnow.info, and www.trimup.info, Defendants' YouTube and social media websites, all Basic Reset/Biogenyx affiliate websites, and any future website(s) created, controlled by, or related to Defendants (collectively, "Defendants' websites"); and any other media over which Defendants have control to determine whether the labeling complies with 21 U.S.C. § 343 and applicable regulations. Defendants shall notify FDA

in writing of the identity and qualifications of the Labeling Expert within three (3) business days of retaining such Labeling Expert;

iv. The Labeling Expert conducts a comprehensive review of Defendants' product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control and certifies in writing to FDA that: (1) he or she has reviewed Defendants' product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control; (2) all labeling violations brought to Defendants' attention by FDA, the Labeling Expert, and any other source have been corrected; and (3) Defendants' products and claims are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The Labeling Expert shall prepare a detailed report of this review, which shall be submitted to FDA, that shall include, but not be limited to, a determination that Defendants have implemented procedures that are adequate to ensure that their product labeling complies with 21 U.S.C. § 343 and applicable regulations;

B. For all of Defendants' drugs, either:

i. an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs; or

ii. the following requirements are met:

a. Defendants remove from product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control (i) all representations that the products diagnose, cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a drug within the meaning of the Act, and (ii) all references, direct or indirect, to other sources that contain representations that

Defendants' products diagnose, cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of Defendants' products to be a drug within the meaning of the Act;

b. Defendants retain, at Defendants' expense, an independent person (the "Drug Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review the representations Defendants make for each of their products on product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control to determine whether Defendants' claims cause any product that they receive, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1). Defendants shall notify FDA in writing of the identity and qualifications of the Drug Expert within three (3) business days of retaining such Drug Expert;

c. The Drug Expert conducts a comprehensive review of Defendants' product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control and certifies in writing to FDA that: (i) he or she has inspected Defendants' Facility; (ii) he or she has identified all of Defendants' products and reviewed Defendants' representations for each product on product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control; (iii) Defendants have removed all representations that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g); and (iv) based upon the Drug Expert's inspection and review, Defendants are operating in conformity with this Decree, the Act, and its implementing regulations. The Drug Expert's written certification shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed. For all products for which Defendants have removed claims that caused

such products to be drugs within the meaning of the Act, and such products meet the definition of a dietary supplement, Defendants shall comply with the requirements in Paragraph 7.A of this Decree, the dietary supplement provisions of the Act, and its implementing regulations, before introducing such products into interstate commerce as dietary supplements;

C. For all of Defendants' devices, either:

i. the devices are: (a) the subject of an approved application for premarket approval under 21 U.S.C. § 360e(a); (b) the subject of an investigational device exemption under 21 U.S.C. § 360j(g); (c) the subject of a cleared premarket notification under 21 U.S.C. § 360(k); or (d) the subject of a grant of *de novo* classification from FDA under 21 U.S.C. § 360c(f)(2); or

ii. the following requirements are met:

a. Defendants remove from product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control (i) all representations that the products diagnose, cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a device within the meaning of the Act, and (ii) all references, direct or indirect, to other sources that contain representations that Defendants' products diagnose, cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of Defendants' products to be a device within the meaning of the Act;

b. Defendants retain, at Defendants' expense, an independent person (the "Device Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review the representations Defendants make for each of their products on product labels; labeling; promotional materials; Defendants' websites; and any

other media over which Defendants have control to determine whether Defendants' claims cause any product that they receive, label, hold, or distribute to be a device within the meaning of 21 U.S.C. § 321(h). Defendants shall notify FDA in writing of the identity and qualifications of the Device Expert within three (3) business days of retaining such Device Expert;

c. The Device Expert conducts an inspection of Defendants' Facility and a comprehensive review of Defendants' product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control and certifies in writing to FDA that: (i) he or she has inspected Defendants' Facility; (ii) he or she has identified all of Defendants' products and reviewed Defendants' representations for each product on product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control; (iii) Defendants have removed all representations that cause any of Defendants' products to be devices within the meaning of the Act, 21 U.S.C. § 321(h); and (iv) based upon the Device Expert's inspection and review, Defendants are operating in conformity with this Decree, the Act, and its implementing regulations. The Device Expert's written certification shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed;

D. Should any of the Experts described in Paragraphs 7.A–C (who can be the same person(s)) identify any deficiencies in their certifications as described in Paragraphs 7.A–C:

i. Defendants shall report in writing to FDA and the appropriate Expert the actions they have taken to correct all such deficiencies; and

ii. For deficiencies related to Defendants' food (including dietary supplements):

a. The CGMP Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s), that Defendants' Facility, methods, processes, and controls used to receive, label, hold, and distribute dietary supplements are and will be continuously operated in conformity with Dietary Supplement CGMP and this Decree; and

b. The Labeling Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s) that Defendants have updated their labels and/or labeling to ensure that Defendants' food is in compliance with this Decree, the Act, and its implementing regulations;

iii. For deficiencies relating to drugs, the Drug Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s), that Defendants have either: (a) removed all representations that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g), from product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control; or (b) ensured that each of Defendants' drugs is the subject of an approved new drug application or an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs;

iv. For deficiencies relating to devices, the Device Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s), that Defendants have either: (a) removed all representations that cause any of Defendants' products to be devices within the meaning of the Act, 21 U.S.C. § 321(h), from product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control; or (b) ensured that each of Defendants' devices are the subject of an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a), the subject of an effective investigational

device exemption pursuant to 21 U.S.C. § 360j(g), the subject of a cleared premarket notification pursuant to 21 U.S.C. § 360(k), or the subject of a grant of *de novo* classification from FDA pursuant to 21 U.S.C. § 360c(f)(2);

E. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in Paragraph 8, all of Defendants' food (including dietary supplements), drugs, and devices that were received, labeled, held, and/or distributed between November 7, 2017, and the date of entry of this Decree;

F. As and when FDA deems necessary, FDA representatives inspect Defendants' Facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations. Provided that FDA finds that Defendants' submissions under Paragraphs 7.A–E of this Decree appear to be satisfactory and notified Defendants of such finding in writing, FDA will initiate the inspection as soon as practicable;

G. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to Paragraph 7, at the rates set forth in Paragraph 15; and

H. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 7.A–G of this Decree. FDA will notify Defendants as soon as practicable. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Within twenty (20) calendar days after entry of this Decree, Defendants shall recall and destroy, under FDA supervision and to FDA's satisfaction, all of Defendants' food (including dietary supplements), drugs, and devices that Defendants received, labeled, held, and/or

distributed between November 7, 2017, and the date of entry of this Decree. Defendants shall, under FDA supervision and to FDA's satisfaction, notify all affected consumers of the recall. Prior to destruction, Defendants must submit a written destruction plan to FDA and FDA must approve Defendants' destruction plan in writing before any destruction can take place. Under no circumstances shall FDA's silence be construed as a substitute for written notification. Defendants shall notify FDA in writing within ten (10) calendar days of receiving any additional recalled products. Defendants shall hold the recalled products until FDA is available to supervise destruction. Defendants shall not dispose of any article of food, drug, or device in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory in which the drugs are disposed. Defendants shall bear the cost of the recall, destruction notification, and FDA supervision. The cost of FDA's participation and supervision under this Paragraph shall be borne by Defendants at the rates specified in Paragraph 15.

9. After Defendants have complied with Paragraphs 7.A–G and received FDA's written notification pursuant to Paragraph 7.H, Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 7.A–C (the "Auditor") to conduct audit inspections of Defendants' Facility no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 7.H. The Auditor may be the same person or persons retained as an Expert described in Paragraphs 7.A–C.

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether or not Defendants are operating in compliance with this Decree, the Act, and its implementing regulations and identifying in detail any deviations from the foregoing ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (1) has personally inspected Defendants' Facility and operations and reviewed all product labels; labeling; promotional materials; Defendants' websites; and any other media over which Defendants have control containing representations about the intended use(s) of Defendants' products; and (2) personally certifies whether or not Defendants' food, drugs, and/or devices are in compliance with the requirements of this Decree, the Act, and its implementing regulations.

C. As a part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA, at the address provided in Paragraph 24, by courier service or overnight delivery service, no later than fifteen (15) business days after the date the Audit inspection is completed. In addition, Defendants shall maintain their Audit Reports and all of their underlying data in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' food, drugs, or devices are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no

circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

10. Upon entry of this Decree and after Defendants receive notification under Paragraph 7.H from FDA that they are permitted to resume operations, Defendants and all Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce: (1) articles of food (including dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343; and (2) devices that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o);

B. Violating 21 U.S.C. § 331(k), by causing articles of: (1) food (including dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded

within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce;

C. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

D. Failing to implement and continuously maintain the requirements of this Decree, the Act, or its implementing regulations.

11. If, at any time after this Decree has been entered, FDA determines, based on a review of inspection results; product labels; labeling; promotional materials; Defendants' websites; any other media over which Defendants have control that contains representations about the intended use(s) of Defendants' products; a report prepared by Defendants' Experts or the Auditor; or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective actions, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease labeling, holding, or distributing any products;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

C. Submit additional reports or information to FDA as requested;

D. Recall any product at Defendants' expense; or

E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with this Decree, the Act, or its implementing regulations. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

12. Upon receipt of any order issued by FDA pursuant to Paragraph 11, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in Paragraph 11, at the rates specified in Paragraph 15.

13. Within ten (10) calendar days after FDA's request for Defendants' labels, labeling, promotional materials, Defendants' websites, and any other media over which Defendants have control containing representations about the intended use(s) of Defendants' products, Defendants shall submit a copy of the requested materials (in hard copy or, if appropriate, on CD-ROM) to FDA at the address specified in Paragraph 24.

14. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers, Defendants' product labels,

labeling, promotional materials, Defendants' websites, and any other media over which Defendants have control containing representations about the intended use(s) of Defendants' products, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, Defendants' product labels, labeling, promotional materials, Defendants' websites, and any other media over which Defendants have control containing representations about the intended use(s) of Defendants' products; and to examine and copy all product labels, labeling, promotional materials, Defendants' websites, any other media over which Defendants have control, and all records relating to the receipt, labeling, holding, or distribution of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $97.57 per hour or fraction thereof per representative for inspection and investigative work; $132.89 per hour or fraction thereof per representative for analytical or review work; $0.58 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendants shall

make payment in full to FDA within twenty (20) business days of receiving written notification from FDA of the costs.

16. Within five (5) business days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at Defendants' Facility and ensure the Decree remains posted for as long as the Decree remains in effect. Within ten (10) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this Paragraph.

17. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this Paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this Paragraph.

18. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all Associated Persons. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this Paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

19. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within five (5) business days of each time that any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this Paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts.

20. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Basic Reset/Biogenyx, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) business days prior to such assignment or change in ownership.

21. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: (a) five thousand dollars ($5,000) in liquidated damages for each violation of the Act, its implementing regulations, or this Decree; (b) an

additional three thousand dollars ($3,000) in liquidated damages per day, per violation, for each violation of the Decree, the Act, and its implementing regulations; and (c) an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of the Decree, the Act, and its implementing regulations. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature, and the remedy in this Paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence" and addressed to Division Director, Office of Human and Animal Food Operations East 5 (HAFE 5), Cincinnati District Office, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237, and shall reference this civil action by case name and civil action number.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this ___ day of _____, 2019.

_____
UNITED STATES DISTRICT JUDGE

Entry consented to:

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FRED R. KAUFMAN III
Individually and on behalf of Basic Reset and Biogenyx

Kimberly Kaufman
KIMBERLY KAUFMAN
Individually

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